



510(K) SUMMARY

APR 04 2013

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at June 15, 2011.

The assigned 510(k) number is: K122194

1. Submitter's Identifications:

Establishment: EVERYWAY MEDICAL INSTRUMENT CO., LTD.

Address: 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shengkeng Hsiang, Taipei Hsien
222, Taiwan

Registration Number: 9616877

Operations: Manufacturer

Owner/Operator: EVERYWAY MEDICAL INSTRUMENT CO., LTD.

Address : 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shengkeng Hsiang, Taipei
Hsien 222, Taiwan

Contact Person: Robert Tu

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2. Name of the Device:

Everyway Incontinence Stimulation Electrode

Model: PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care Vaginal
Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe.

3. Information of the 510(k) Cleared Device (Predicate Device):

Hollister Vaginal Stimulation/EMG Probe-Tampon (K971541) and Anal Stimulation/EMG
Probe-w/Stop(K990456)

4. Classification Information:

Trade/Device Name: Everyway Incontinence Stimulation Electrode, model PR-02/02A,
PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care Vaginal
Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe.

Regulation Number: 21 CFR Part 876.5320 & 21 CFR Part 884.1425

Classification Name: Stimulator, Electrical, Non-implantable, For Incontinence & Perineometer.

Regulatory Class: II

Product Code: KPI & HIR

5. Device Description:

The Life-Care Vaginal Probe models PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A are the light weight cylinder consisting of two or three independent conductive rings or plates that are paired and isolated, physically and electrically. The cylinder is shaped with a waist and handle for comfort positioning in vaginal canal for incontinent treatment as above mentioned and easy for removing after treatment. It is watertight to allow for washing with soap and water between uses. The electrode is designed for repeated intermittent use in home or clinic for up to one year by a single user. It does not require sterilization, but does required washing for reuse according to the validated cleaning method as recommended in user manual.



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The Life-Care Anal Probe models PR-06/06A, PR-12A, PR-13/13A are the light weight cylinder consisting of two or three independent conductive rings that are paired and isolated, physically and electrically. The cylinder is shaped with a waist and handle for comfort positioning in rectal canal for incontinent treatment as above mentioned and easy for removing after treatment. It is watertight to allow for washing with soap and water between uses. The electrode is designed for repeated intermittent use in home or clinic for up to one year by a single user. It does not require sterilization, but does required washing for reuse according to the validated cleaning method

To fit with different type of device connection, the lead wire of device was provided with two different type of wire connection terminals, the standard female plug terminal and pigtail terminal. For the model with pigtail connection terminal, the letter "A" in the last of model name (e.g. PR-02A) to separate them from the model with standard female plug terminal.

6. Intended Use:

The Everyway Incontinence Stimulation Electrode, model PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care Vaginal Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

7. Comparison to the 510(k) Cleared Device (Predicate Device):

The following features are completely identical among the predicate device and our devices.

Electrode Characteristics	Vaginal Probe		Anal Probe	
	Predicate device	New Device	Predicate Device	New Devices
Model	Hollister K971541 Vaginal Stimulation/ EMG Probe-Tampon	Everyway Vaginal Stimulation /EMG Probe, PR-02 / PR-02A, PR-03 / PR-03A, PR-04 / PR-04A, PR-10A, PR-11A, PR-14A	Hollister K990456 Anal Stimulation/ EMG Probe-w/Stop	Everyway Vaginal Stimulation /EMG Probe, PR-06 / PR-06A, PR-12A, PR-13 / PR-13A
Usage Conditions	Reusable-Single Patient	Same	Reusable-Single Patient	Same
Electrode Material	Stainless steel	Same	Stainless steel	Same
Electrode Placement	Vaginal	Same	Anal	Same
Contact Duration	Intermittent mucosal contact<30 min/ session- Stim<1 hour/session- EMG not exceeding 1 hr combined	Same	Intermittent mucosal contact <30 min/ session- Stim<1 hour/session- EMG not exceeding 1 hr combined	Same
Indications for Use	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles	Same	Electrical stimulation of the pelvic floor muscles for the treatment of urinary incontinence. EMG sensing of the pelvic floor muscles	Same



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Different Features Assessment:

As mentioned on the comparison table, there exists the following feature difference:

- 1> Electrode orientation: PR-02/02A new device provide the shell type of orientation, the other models provide circular type of orientation.
- 2> The number of electrodes: PR-10A/PR-11A for Everyway Vaginal probe and PR-12A for Everyway Anal probe provide 3 independent stimulation channels. The other models provide 2 independent stimulation channels.
- 3> Device Connector: For Everyway's probes two different type of connectors are provided, the cord with standard plug and the cord with pigtail plug. But for the predicate device, only the cord with standard plug is to be provided.
- 4> The dimensions of the device is different as the following table:

● For Vaginal Probe:

Probe Diameter(inches)	Predicate device	New Devices					
Model	Hollister/K971541	PR-02/02A	PR-03/03A	PR-04/04A	PR-10A	PR-11A	PR-14A
Probe Length(inches)	2.3	2.91	5.83	3.97	5.4	4.09	2.07
Probe Diameter(inches)	0.841	1.1	0.98	0.78	0.98	0.78	0.78
Electrode Spacing(inches)	0.50	0.71	0.61	0.57	0.18, 0.20	0.1, 0.18	0.57
Active Surface	0.90	1.186	1.22	0.97	0.97, 1.22	0.97	0.93
Area(inch ² /band)							

● For Anal Probe:

Probe Diameter(inches)	Predicate device	New Device		
Model	Hollister/K990456	PR-06/06A	PR-12A	PR-13/13A
Probe Length(inches)	2.349	3.42	4.27	4.27
Probe Diameter(inches)	0.453	0.51	0.77	0.77
Electrode Spacing(inches)	0.25	0.31	0.1, 0.12	0.42
Active Surface Area (inch ² /band)	0.35	0.3	0.35, 0.38	0.58

Since most of significant features of the predicate device and our new device as the following listing are completely identical, we considered it is reasonable to claim substantial equivalence between our new device and predicate device:

- 1> Usage Conditions..
- 2> Body Material.
- 3> Electrode(Conductive) Material.
- 4> Electrode Placement.
- 5> Contact Duration.
- 6> Indication for Use

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of the devices are as the followings:

- 1> The assessment and test report for the device performance performed by manufacturer.
- 2> The validation test report for the recommended cleaning method for reuse conducted and reported by the manufacturer.
- 3> The biocompatibility conformity test report according to ISO 10993-5 and ISO 10993-10 performed by the accredited testing laboratory.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:

No particular Clinical Test was conducted for Everyway Incontinence Stimulation Electrode.



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10. Conclusions

The Everyway Incontinence Stimulation Electrode, model PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care Vaginal Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe, has the same intended use and technological characteristics as the cleared device of Hollister Vaginal Stimulation/EMG Probe-Tampon (K971541) and Anal Stimulation/EMG Probe-w/Stop(K990456). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted model could maintain the same safety and effectiveness as that of cleared device.

In the other words, Everyway Incontinence Stimulation Electrode, model PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care Vaginal Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe are substantial equivalent with the Hollister Vaginal Stimulation/EMG Probe-Tampon (K971541) and Anal Stimulation/EMG Probe-w/Stop(K990456)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

April 4, 2013

EVERYWAY MEDICAL INSTRUMENTS CO., LTD.
% Mr. Robert Tu
President and Operator Owner
3FL., No. 5, Lane 155, Section 3, Peishen Rd.
SHENKENG HSIANG, TAIPEI HSIEN
CHINA (TAIWAN) 222

Re: K122194

Trade/Device Name: Everyway Incontinence Stimulation Electrode, model PR-02/02A,
PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care
Vaginal Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care
Anal Probe

Regulation Number: 21 CFR§ 876.5320

Regulation Name: Nonimplanted electrical continence device

Regulatory Class: II

Product Code: KPI, HIR

Dated: March 25, 2013

Received: March 29, 2013

Dear Mr. Tu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.

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Indications For Use

510(k) Number (if known): K122194

Device Name: Everyway Incontinence Stimulation Electrode, model PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care Vaginal Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe.

Indications For Use:

The Everyway Incontinence Stimulation Electrode, model PR-02/02A, PR-03/03A, PR-04/04A, PR-10A, PR-11A, PR-14A for Life-Care Vaginal Probe & PR-06/06A, PR-12A, PR-13/13A for Life-Care Anal Probe are intended to provide electromyographic feedback from pelvic musculature or electrical stimulation to pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary incontinence.

Prescription Use √
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and
Urological Devices

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